UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)(KMW)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' REPLY IN SUPPORT OF *DAUBERT* MOTION TO EXCLUDE OPINIONS OF WAYNE GIBSON

SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
jdavis@slackdavis.com

HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102
Tel.: 267-435-1300
ruben@honiklaw.com

On the Brief:
John R. Davis, Esq.
Ruben Honik, Esq.

I. INTRODUCTION

Mr. Gibson's deployed "ostrich behavior" for his expert analysis. Right at the point where further analysis would have risked sinking his opinions, Mr. Gibson conveniently looked no further. This is the hallmark of a non-rigorous methodology, and this Court should preclude Mr. Gibson's opinions pursuant to Rule 702.

II. LAW AND ARGUMENT

A. IQVIA Data is the "Gold Standard"

Everyone in this litigation (save for Mr. Gibson himself) recognizes IQVIA to be the "gold standard." This includes Defendants' own employees, Defendants' other experts, Dr. Conti and countless others in academia who (unlike Mr. Gibson) routinely publish peer-reviewed articles relying on IQVIA pricing data, the pharmaceutical and healthcare industries, and this Court recently in denying Defendants' decertification motion. Mr. Gibson quite literally stands alone.

Mr. Gibson now distances himself from his lone source of direct "evidence" regarding any flaws in the IQVIA Xponent data, a single inadmissible unauthenticated hearsay email forwarded to him by counsel for Defendants. Mr. Gibson now pivots instead to relying on certain boilerplate language in IQVIA's data that (a) are nowhere to be found in Mr. Gibson's reliance materials for his two expert reports, and (b) do not support his contentions, especially when viewed in context.

For instance, Mr. Gibson highlighted a single legal disclaimer in an IQVIA Data Disclosure Policy[1] regarding the potential for "error and variance" and that IQVIA "offers no assurances that the IQVIA Data will be suitable for use as evidence in any Legal Proceeding." There is nothing remarkable about such a statement made by a company in a legal disclaimer. This says nothing more than courts decide the admissibility of evidence. Mr. Gibson omits the remainder of the paragraph, which reads as follows:

> "[I]t should be advised that IQVIA Data may reflect projections, estimates, and forecasts that are the result of a combination of confidential and proprietary technologies, statistical methodologies and a significant number of sources. These estimates reflect the independent judgment, expertise and opinion of IQVIA representatives to arrive at ***a reasonable approximation of market activity***. The IQVIA Data is intended to support sales, marketing and ***research applications, and it is highly reliable*** for those purposes."[2]

IQVIA is a "reasonable approximation of market activity[,]" which happens to mirror the standard in the Third Circuit for a class damages model. *Rossi v. Standard Roofing, Inc*., 156 F.3d 452, 484 (3d. Cir. 1998) ("[T]he jury is permitted to calculate the actual damages suffered using a 'reasonable estimate, as long as

[1] In discussing this document here, Plaintiffs do not waive any objection to Mr. Gibson's use or reference to it given that it appears nowhere in his reliance materials and was introduced at the end of his second deposition by Defendants' counsel on re-direct.

[2] https://www.iqvia.com/about-us/third-party-access-program/-/media/86a441b5b9be415a9ead325fbfd43b10.ashx#:~:text=➢%20Consent%20for%20the%20disclosure,from%20unnecessary%20and%20unlimited%20disclosure (last visited March 6, 2024).

the jury verdict is not the product of speculation or guess work'[.]" (internal quotations and citations omitted)).

In contrast to IQVIA's robust 93% coverage (a term which Mr. Gibson disputes, but admits he has no understanding and did not investigate what it means (Opp'n, at 9)), the other datasets Mr. Gibson uses to contrast with IQVIA are incomplete, non-representative, and/or based on data not prepared at the point of sale.

For instance, Defendants appear to misrepresent that MSP's assignors' claims data is comparable to equivalent data in IQVIA, and that the IQVIA data purportedly yields higher 'damages' for the assignors. (Opp'n, at 7.) That is not the case. There is no apples-to-apples comparison to be done here. The comparison Mr. Gibson makes is the average pricing in IQVIA *across the entire class* to the very limited sample of MSP's assignors' data. To give an idea of just how small this sample is, the MSP assignor damages represent approximately 0.07% of the total IQVIA-based class damages. Mr. Gibson's attempt to extrapolate from such a miniscule sample presents as an unreliable methodology.[3] He essentially tries to average together two different averages, which is utterly unhelpful and unreliable. *See, e.g.*, *Ziegler v.*

[3] Defendants highlight that Dr. Conti did calculate MSP damages based on the assignor data in one of her expert reports. (Opp'n, at 7-8.) That report, however, was prepared at a time when the Court was contemplating an *individual* trial and not the class trial that is now proceeding.

Polar Indus., Inc., No. 23-cv-0112, 2024 WL 482212, at *5-6 (W.D.N.C. Feb. 7, 2024) (precluding expert who attempted to average together five different averages).

Mr. Gibson also highlights a comparison between a publicly available CMS Part D summary file, and the IQVIA data. However, the CMS Part D summary is collected from Prescription Drug Event ("PDE") data that is submitted to CMS long after the point of sale. Mr. Gibson and Defendants never purchased the underlying PDE data (as they could have). Moreover, the Part D summary may reflect channels of valsartan prescribing not included in IQVIA (certainly the inverse is true) as well as post-point of sale adjustments to the extent they would be calculable at the point of sale.

Finally, Defendants aver that the Pharmacy Defendant Data is superior to IQVIA because of some unspecified ability to "validate" in their words. (Opp'n, at 8.) This red herring "benefit" is totally unnecessary given IQVIA's rigorous data quality checks.[4] Defendants largely ignore (just as Mr. Gibson did) the extreme limitations of the Pharmacy Defendant Data: (1) this dataset represents only a

[4] Another one of the documents not relied on by Mr. Gibson, but nevertheless introduced on re-direct at the end of his second deposition, is an IQVIA "Published Specifications" document, which states that "[m]ore than one hundred statisticians support the development of sample designs and projection methodologies to estimate activities to achieve a high degree of accuracy on a cost effective basis." *See* https://www.iqvia.com/-/media/iqvia/pdfs/about-us/tpa/client-materials/iqvia-information-services-published-specifications-january-2018.pdf (last visited March 6, 2024).

small fraction of the IQVIA quantities of Defendants' at-issue VCDs, omitting hundreds of millions of quantities captured by the significantly more robust IQVIA dataset;[5] (2) it represents exclusively prescriptions dispensed through large chain pharmacies and grocery stores where peer-reviewed studies have shown generic drugs to be significantly cheaper; and (3) it significantly overrepresents mail-order prescriptions that are also known to be significantly cheaper. (*See* Mot., at 10-16.)

For instance, Defendants' Opposition effectively concedes that Mr. Gibson engages in unreliable *ipse dixit* conclusion jumping. Despite acknowledging the variability of pricing of generic drugs, and admitting he did not examine how that variability manifested itself, including with respect to large chain pharmacies, Mr. Gibson opines that it has "no impact" on his analysis. This conclusion however is unsupported by any methodology (or explanation of any kind), and it does have an impact. Mr. Gibson significantly relies on the Pharmacy Defendant Data to attempt to undermine IQVIA, but did not examine how this limitation could (indeed, would) affect that data's overall reliability. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either Daubert or the Federal Rules of Evidence requires

[5] As discussed in the Motion and touched on *infra*, where the Pharmacy Defendant Data does capture a significant portion of the total IQVIA sales, the pricing data significantly aligns, further reinforcing, as Dr. Conti testified, the superiority of the IQVIA data.

a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Defendants attempt to salvage Mr. Gibson's opinion by claiming that Dr. Conti likewise calculated damages based on the Pharmacy Defendant Data. Dr. Conti made such a calculation at the request of counsel. And as set forth by Dr. Conti at her deposition and in Plaintiffs' *Daubert* Opposition, Dr. Conti's detailed, fact-based conclusion, based on rigorous analysis, is that the IQVIA data is the most reliable dataset for determining class damages here.

Finally, Defendants play a numbers game to attempt to undermine Dr. Conti's analysis demonstrating, crucially, that as the Pharmacy Defendant Data begins to approximate IQVIA in terms of quantities, the prices become much more similar. Examples of this phenomenon include both Torrent VCDs and ZHP valsartan-HCTZ products where the Pharmacy Defendant Dataset captures approximately 75% and 70%, respectively, of the IQVIA reported quantities. (*See* Mot., at 14-15 (citing Conti Supp'l Rep.).) Defendants push back on the Torrent example only by stating that the average price still differs by approximately 20%. First of all, even with much more of Torrent's overall VCDs (as encompassed by IQVIA) accounted for, there are still 25% of Torrent VCDs (roughly 10 million quantities) that the Pharmacy Defendant Data does include in its much more limited analysis. And given the makeup of the Pharmacy Defendants, those non-

included prescriptions were necessarily overwhelmingly filled at independent mom-and-pop pharmacies where generic costs have been shown to be higher in peer-reviewed literature cited by Dr. Conti. Second, a 20% difference might seem larger than it actually is in this context. Given the relatively low per-pill prices, 20% often is a matter of a few pennies difference.

Mr. Gibson's circular reasoning (i.e., IQVIA is different therefore it is wrong) is unsupported by any rigorous analysis as he failed to account for (or even consider) the significant limitations of his other so-called "benchmarks."

B. Defendants' Attempt to Avoid the Collateral Source Rule Falls Flat

Defendants' attempt to both invoke collateral source payments by Medicare/CMS ("CMS"), and at the same time avoid application of the collateral source rule, falls flat on its face.

First, as pointed out by Plaintiffs in the Motion, the "direct subsidy" and the "risk corridor" subsidy have *nothing to do with valsartan prescriptions* in particular. (Mot., at 7-8.) The "direct subsidy" is paid out prospectively, on a per capita basis, based on composite health conditions of a predicted set of insureds (not particular patients nor particular therapies), and as Defendants well know, there are myriad options for treatment of hypertension. There is simply no basis to argue that Dr. Conti should account for this unrelated payment in her damages model, or even for Defendants to claim credit for it as a collateral source. The same

is true of the "risk corridor" subsidy, which Defendants now abandon as a criticism of Dr. Conti. (Opp'n, at 21 & n.6.)

Defendants also myopically attempt to paint Plaintiffs' express warranty claim as exclusively sounding in contract, in their hope to avoid application of the collateral source rule, despite acknowledging that Plaintiffs' other claims for this trial sound in tort. (Opp'n, at 26-27.) This claim-by-claim approach ignores that courts should look at the overall nature of the case in deciding whether it sounds in tort or contract, not the individual claims. *See, e.g., Hill v. Hartness*, 536 S.W. 3d 649, 654 (Ark. App. 2017) (look to whether the complaint "as a whole sounds in tort or contract (i.e., whatever the 'gist' of the complaint)"); *R.J. Reynolds Tobacco Co. v. Schoeff*, 178 So. 3d 487, 492 (Fla. Dist. Ct. App. 2015) ("look to the substance of the action and not the conclusory terms used by the parties"); *Abraxas Petr. Corp. v. Hornburg*, 20 S.W. 3d 741, 752-53 (Tex. Ct. App. – El Paso 2012) (look to the "substance"); *Yao v. Chapman*, 705 N.W. 2d 272, 284 (Wis. 2005) ("We also may look to the complaint in its entirety to see if, as a whole, it sounds in tort or contract.").

Where Defendants' conduct is both violative of contractual and tort duties, the policy rationales behind the collateral source rule is equally forceful as if this were a tort case solely. Defendants' own case citations highlight that the court's focus in determining whether the collateral source rule should apply is whether the

policy considerations for its application (*i.e.*, favoring a *potential*[6] double recovery for the plaintiff versus providing a windfall for the defendant). *See, e.g., Asher v. Unarco Material Handling, Inc.*, 862 F. Supp. 2d 551, 555 (E.D. Ky. 2012) (discussing policy reasons as driving force behind collateral source rule); *United States v. City of Twin Falls, Idaho*, 806 F.2d 862, 873–74 (9th Cir. 1986) ("Thus, if there must be a double recovery, the law prefers that the injured victim receive it rather than the tortfeasor."); *see generally* Pls.' Mot. in Limine (collecting cases that excluded evidence from jury of government payments under collateral source rule or similar principles). Defendants here, if found liable for the causes of action to be tried, are "tortfeasors" and the public policy reasons behind applying the collateral source doctrine militate against giving ZHP, Teva, and Torrent a windfall, when each recklessly (and even intentionally) sold valsartan contaminated with potent human carcinogens to be consumed by patients and paid for by those patients' TPPs.

Fully aware that they will likely have to face the collateral source rule head on, Defendants also point to a handful of jurisdictions that supposedly limited or abolished the collateral source rule. (Opp'n, at 25 & n.7.) However, Defendants

[6] CMS very well could attempt to seek repayment of any amounts, if any, CMS may claim to be owed to CMS. A full judgment (*i.e.,* not offsetting any collateral source payments) ensures that TPPs are not left "holding the bag" for Defendants' wrongful conduct.

ignore the specifics. Those statutes are: (1) limited to the context of personal injury and/or medical malpractice cases or otherwise inapplicable here;[7] and (2) all specify that the issue of collateral source reduction is for the court to determine post-trial and that no collateral source evidence is allowed to be presented to a jury.[8] Accordingly, even if these statutes are applicable here (they are not), Mr.

[7] NY CPLR 4545 (limited to "personal injury" cases where plaintiff is seeking "to recover for the cost of medical care, dental care, custodial care or rehabilitation services, loss of earnings or other economic loss" and expressly inapplicable where there is a "statutory right of reimbursement" as there may potentially be here); Mich Stat. § 600.603 (limited to "personal injury" actions); Alaska Stat. § 09.55.548 (limited to "medical malpractice" actions and explicitly excluding "federal program" collateral sources from scope); ALM GL ch. 231, § 60G (limited to medical malpractice actions); Minn. Stat. § 548.251 (limited to "payments related to the injury or disability" of the plaintiff and clearly limited to personal injury or medical malpractice cases); Fla. Stat. § 768.76(2) (limited to negligence claims and "there shall be no reduction for collateral sources for which a subrogation or reimbursement right exists"); CT Gen. Stat. § 52-225a & b (limited to "personal injury or wrongful death" actions).

[8] NY CPLR 4545 ("Any collateral source deduction required by this subdivision shall be made by the trial court after the rendering of the jury's verdict. The plaintiff may prove his or her losses and expenses at the trial irrespective of whether such sums will later have to be deducted from the plaintiff's recovery."); Mich Stat. § 600.603 (collateral source evidence admissible only only "after a verdict for the plaintiff and before a judgment is entered on the verdict"); ALM GL ch. 231, § 60G (to be presented after jury returns verdict); Minn. Stat. § 548.251, Subd. 5 ("The jury shall not be informed of the existence of collateral sources or any future benefits which may or may not be payable to the plaintiff."); Fla. Stat. § 768.76(2) (court reduces after jury verdict); CT Gen. Stat. § 52-225a(b) ("Upon a finding of liability and an awarding of damages by the trier of fact and before the court enters judgment, the court shall receive evidence from the claimant and other appropriate persons concerning the total amount of collateral sources which have been paid for the benefit of the claimant as of the date the court enters judgment.").

Gibson's testimony regarding CMS subsidies is inappropriate for the jury to hear and his opinions should be excluded.

Defendants try to avoid on-point case law by arguing that they are not "tortfeasors." (Opp'n, at 29 (attempting to distinguish from the very much on-point *In re HIV* decision).) This is nothing more than a denial of liability that the Court should reject outright.

C. The Court Should Exclude Mr. Gibson's DIR Opinions

Defendants argue that Mr. Gibson's DIR related opinions are grounded in fact, but cite no facts and no evidence to support any DIR calculations. This is an offset on which Defendants unquestionably bear the burden of proof. Defendants have simply failed to meet that burden. Defendants try to save the opinion by complaining that DIR amounts are in the hands of TPPs, but Defendants never obtained that information. Absent "sufficient facts or data," Mr. Gibson's say-so about what unidentified, unproduced data might show is exceedingly speculative and, therefore, unreliable and unhelpful. Even for the assignors who produced voluminous data about their own transactions to Defendants, Mr. Gibson failed to identify and calculate a single amount that he believes is a valsartan DIR amount that should offset damages. That is because, as stated in the Motion and by Defendants' own pharmacy co-defendants, there is no such thing as "valsartan DIR." (Mot., at 9.)

The Court should preclude Mr. Gibson from offering this speculative opinion not grounded in any factual evidence to the jury.

Dated: March 6, 2024

Respectfully submitted,

/s/ John R. Davis
SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Tel.: 512-795-8686
Fax: 512-795-8787
jdavis@slackdavis.com

/s/ Ruben Honik
HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102
Tel.: 267-435-1300
ruben@honiklaw.com

MDL PEC AND/OR CO-LEAD COUNSEL FOR THE PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2024, a true and correct copy of the foregoing was filed and served via the Court's CM/ECF system.

/s/ David J. Stanoch
David J. Stanoch